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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,176

12/20/2005

Darla Onichtchouk

8054-005-US

1822

32301 7590 03/08/2007  
CATALYST LAW GROUP, APC  
9710 SCRANTON ROAD, SUITE S-170  
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EXAMINER

LEE, JAE W

ART UNIT	PAPER NUMBER
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1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

03/08/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

**Application No.**

10/551,176

**Applicant(s)**

ONICHTCHOUK ET AL.

**Examiner**

Jae W. Lee

**Art Unit**

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Application status***

Claims 1-32 are pending in the instant application.

It is noted by the Examiner that Claims 5-14, 19, 27, 28 and 30 are improperly multiply dependent Claims.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, 19, 20 and 27-31, drawn to a pharmaceutical composition comprising a nucleic acid molecule encoding DG931 protein or functional fragment thereof and an effector or modulator of said nucleic acid molecule or said protein or protein fragment, and their uses.

Group II, claim(s) 15, drawn to a use of a DG931 nucleic acid molecule or a polypeptide encoded thereby or a fragment or a variant of said nucleic acid molecule or said polypeptide or an effector or modulator of said nucleic acid or polypeptide for the 1) manufacture of a medicament for the treatment of diabetes, obesity, or metabolic syndrome.

Group III, claim(s) 15, drawn to a use of a DG931 nucleic acid molecule or a polypeptide encoded thereby or a fragment or a variant of said nucleic acid molecule or said polypeptide or an effector or modulator of said nucleic acid or polypeptide for 2) controlling the function of a gene or a gene product which is influenced or modified by a DG931 polypeptide.

Art Unit: 1656

Group IV, claim(s) 16, drawn to a use of a DG931 nucleic acid molecule or use of a nucleic acid molecule encoding DG931 or a homologue thereof or use of a polypeptide encoded thereby, or use of a fragment or a variant of said nucleic acid molecule or said polypeptide, or use of an effector or modulator of said nucleic acid molecule or said polypeptide for identifying substances in vitro capable of interacting with a DG931 polypeptide.

Group V, claim(s) 17 and 18, drawn to a non-human transgenic animal exhibiting a modified expression of a DG931 polypeptide.

Group VI, claim(s) 21, drawn to a method of identifying a (poly) peptide involved in the regulation of energy homeostasis or metabolism in a mammal comprising the steps of (a) contacting a collection of (poly)peptides with a DG931 homologous polypeptide or a fragment thereof under conditions that allow binding of said (poly)peptides; (b) removing (poly)peptides which do not bind and (c) identifying (poly)peptides that bind to said DG931 homologous polypeptide.

Group VII, claim(s) 22 and 23, drawn to a method of screening for an agent which effects or modulates the interaction of a DG931 polypeptide with a binding target comprising the steps of (a) incubating a mixture comprising (aa) a DG931 polypeptide or a fragment thereof; (ab) a binding target or agent of said DG931 polypeptide or fragment thereof; and (ac) a candidate agent under conditions whereby said polypeptide or fragment thereof specifically binds to said binding target at a reference affinity; (b) detecting the binding affinity of said DG931 polypeptide or fragment thereof to said binding target to determine an affinity for the agent; and (c) determining a difference between affinity for the agent and reference affinity.

Group VIII, claim(s) 24 and 25, drawn to a use of a (poly)peptide as identified by the method of claim 21 or of an agent as identified by the method of claim 22 or 23 for the preparation of a pharmaceutical composition for the treatment, alleviation or prevention of metabolic diseases or dysfunctions, including diabetes, obesity, or metabolic syndrome.

Group IX, claim(s) 26, drawn to a use of a (poly)peptide as identified by the method of claim 21 or of an agent as identified by the method of claim 22 or 23 for the preparation of a pharmaceutical composition for the treatment, alleviation or prevention of metabolic diseases or dysfunctions, including diabetes, obesity, or metabolic syndrome.

Group X, claim(s) 32, drawn to a kit comprising (a) a DG931 nucleic acid molecule or a functional fragment or an isoform thereof; (b) a DG931 amino acid molecule or a functional fragment or an isoform thereof; (c) a vector comprising the nucleic acid of (a); (d) a host cell comprising the nucleic acid of (a) or the vector of (b); (e) a polypeptide encoded by the nucleic acid of (a), expressed by the vector of (c) or the host cell of (a);

Art Unit: 1656

(f) a fusion polypeptide encoded by the nucleic acid of (a); (g) an antibody, an aptamer or another effector or modulator of the nucleic acid of (a) or the polypeptide of (b), (e), or (f); (h) an anti-sense oligonucleotide of the nucleic acid of (a); or (i) a combination thereof.

In addition to the above election, please elect a single SEQ ID NO. This

application contains claims directed to the following patentably distinct species:

SEQ ID NO: 1, or SEQ ID NO: 2. Each sequence represents structurally different nucleic acid and/or amino acid sequences. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-32 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Please note that below restriction requirement is for all of the Groups I-X above.

In addition to the above elections, please elect a product from (A)-(D) as listed in claim 1 (see below) that corresponds to the SEQ ID NO, which Applicants have elected above. Therefore, please elect a product from:

- (A) a nucleic acid molecule encoding DG931
- (B) an effector
- (C) a modulator
- (D) DG931 protein

Each product is structurally and functionally different from each other. Therefore, they have different designs, modes of operation, and effects, and they do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over

Art Unit: 1656

the prior art. Agarwal et al. (WO/2002/022802) teach a nucleic acid molecule encoding DG931 and its amino acid sequence that is identical Applicant's DG931 sequence (please see pg. 24 and 36), which corresponds to the limitation of claim 1, in the recitation of "a nucleic acid molecule encoding DG931 protein," and thus, the shared technical feature of the groups is not a "special technical feature", unity of invention between the groups does not exist.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Because these inventions are unrelated and distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Group is not required for another thereby presenting a search burden on the Examiner, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

Art Unit: 1656

remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen K. Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

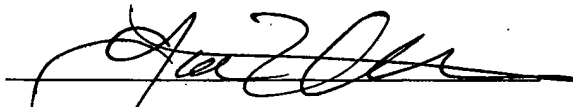
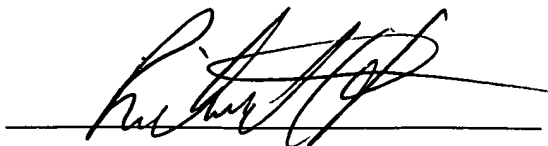
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Application/Control Number: 10/551,176

Page 8

Art Unit: 1656

  
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Patent Examiner: Jae W. Lee, Ph.D.  
\_\_\_\_\_

RICHARD HUTSON, PH.D.  
PRIMARY EXAMINER